

## **REMARKS**

The Office Action, dated November 4, 2005, rejected pending claims 54-76. The present amendment deletes claim 60 and amends claim 61 to spell out the acronym "GRAS" as "generally regarded as safe". This amendment finds support in paragraph 30 ([030]) of the specification, thus, no new matter is added by these amendments.. Upon entry of the present amendment, claims 54-59, 61-76 will be pending.

### **I. Information Disclosure Statement**

Applicants note with appreciation that the Office has considered the information disclosure statement (IDS) submitted on August 16, 2005.

### **II. Prior Rejections**

Applicants note with appreciation that the Office has withdrawn the rejections under 35 U.S.C. 102(b) and 103(a) with respect to claims 1-17 and 1-40, respectively, in view of the amendments and arguments previously presented. Office Action at page 2.

### **III. New Rejections**

#### **A. Claim Objections**

The Office objected to the acronym in claim 61 and required Applicants to spell out the acronym followed by the acronym in parenthesis. Office Action at Page 3. Applicants have amended claim 61 accordingly and respectfully request withdrawal of the objection.

#### **B. Rejection of Claims 54 and 60 Under 35 U.S.C. 112, 2<sup>nd</sup> paragraph**

The Office rejected claims 54 and 60 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as being allegedly indefinite and lacking antecedent basis, respectively.

The Office rejected claim 60 as lacking antecedent support for the recitation “wherein the low temperatures is at about 4°C” . Office Action at page 3. Without acquiescence and solely to facilitate prosecution, Applicants cancel claim 60.

The Office rejected claim 54, stating that “It is unclear what ‘a time sufficient to permit the production of a collagen composition actually’ is. A ‘time sufficient’ is an extremely subjective limitation ... can be interpreted to mean from 1 minute to 10 years.” Office Action at page 3. Applicants respectfully traverse. As it is well established, the test for definiteness under 35 U.S.C. 112, second paragraph, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, (Fed. Cir. 1986) and MPEP 2173.02 at 2100-206 (8th ed. rev. 2, May 2004). In addition, the definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the particular application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art the time the invention was made. MPEP 2173.02 at 2100-205 (8th ed. rev. 2, May 2004). Indeed, the Federal Circuit has expressly found that a claim directed to a “period sufficient” was not indefinite, given a disclosure of a preferred treatment period in the patent specification. *Exxon Research and Engineering Co. v. United States*, 60 USPQ2d 1272, 1279 (Fed. Cir. 2001). There, the court observed that:

Although the patent does not quantify the ‘period sufficient’ limitation by reference to any specific period or range of periods, it does not leave those skilled in the art entirely without guidance as to the scope of the requirement ... the specification does not give a specific example of a

period of time sufficient ... however, a preferred treatment period is provided.

The present specification expressly describes a fermentation time of about 18-48 hours for various types of tissues. Examples 2, 3, 4, and 6 specifically disclose about 18-48 hours of fermentation of avian tissues, porcine tissues, aquatic animal tissues, and chicken cartilages, using bacteria. Example 5 specifically discloses about 48 hours of fermentation of avian tissues, using yeast. These examples of specific fermentation periods in the specification provide more than sufficient guidance on preferred fermentation times for obtaining collagen. In light of these express disclosures, a person of ordinary skill in the art would clearly understand the meaning of "a time sufficient" for fermentation. Accordingly, Applicants respectfully request that this rejection be withdrawn.

### **C. Rejection of Claims Under 35 U.S.C. 112, 1<sup>st</sup> paragraph**

#### **a. Rejection of Claims 54-63 and 65-67**

The Office rejected claims 54-63 and 65-67 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Specifically, the Office stated that "the specification, while being enabling for a method of producing collagen monomers by fermenting ... with ... *Bacillus*, *Lactobacillus* or *Pseudomonas*, does not reasonably provide enablement for the use of every single kind of microorganisms in existence." Office Action at page 4. Because the Office has not established a prima facie case of non-enablement, this rejection is respectfully traversed.

Contrary to the Office's statement that "the directions and guidance in the specification is drawn exclusively to the genus *Bacillus* and no other examples or explanations exist", the specification demonstrates the use of both prokaryotes and

eukaryotes in the fermentation process to produce collagen monomers. Examples 2-4 and 6 demonstrated the use of *Bacillus*, a prokaryote, in fermentation to produce collagen monomers. Example 5 demonstrated the use of yeast, an eukaryote, in fermentation to produce collagen monomers. Thus Applicants have enabled fermentation well beyond *Bacillus*. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**b. Rejection of Claims 54-76**

The Office rejected claims 54-76 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Specifically, the Office stated that "... an essential missing element and step in the method and process is how a skilled artisan obtains only the  $\alpha$  form. It is wholly unclear in the claims and in the specification, how this result is even achieved" Office Action at page 6. Applicants respectfully traverse. The specification provides a number of paragraphs that indicate that the fermentation process leads to collagen monomer production. For example, Applicants note in the Summary of the Invention at [0010] that:

Collagens extracted by fermentation have an increased purity, comprising mostly of well preserved collagen monomers...

Later, [0040] provides:

Once collagen-containing tissues are being subjected to the fermentation process, collagen composition comprising mostly of collagen monomers can be readily extracted therefrom in much higher yield, as compared to yields from other method of the art.

Similarly, [0047] states that:

The present invention is also directed to a collagen product comprising the collagen monomers obtained from collagen containing tissues via fermentation.

Finally, [0051] notes that:

However, collagen extraction via fermentation as described in the present invention can result in well-preserved collagen monomers, which can serve as a valuable collagen source for commercial and medical use.

Accordingly, the specification more than amply indicates that fermentation provides the means to obtain mostly collagen monomers (the  $\alpha$  form). Of course, the specification also indicates that the invention provides for extracting the collagen monomers so produced by acidic solubilization (often in the presence of enzyme) followed by precipitation by the addition of salt. See, for example, [0014], [0023], [0040], and [0043]. In any event, the specification does provide the teaching believed absent by Office.

The Office also stated that “nowhere is it described how simply fermenting collagen will ultimately give rise to one particular form/component of collagen ... over another form/component ... predictability of the art suggests that simply fermenting collagen with microorganisms is not going to single handedly produce one form/component over the other, and there ... need to be at the minimum at least one additional step of some sort”. Office Action at page 7. Again, Applicants respectfully traverse. The Office has not met its burden on enablement. As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971) (also cited in MPEP 2164.08 at 2100-198 (8th ed. rev. 2, May 2004)), it is incumbent on the Office to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up its assertions with acceptable evidence or reasoning which is inconsistent with contested statement; otherwise there would be no need for the applicant to go to the trouble of supporting his presumptively accurate disclosure. Indeed, unless there is reason to doubt the objective truth, a disclosure that corresponds to the scope of subject matter sought to be patented should be taken as in compliance with the enablement

requirement. MPEP 2164.04 at 2100-189. Here, the Office only expressed its doubts about obtaining collagen monomers through fermentation, asserting the art suggests fermenting collagen with microorganism will not produce one form over the other form but not providing any evidence or reasoning to back up its assertions. See Office Action at page 7.

The Office does suggest that "Applicant's own examples add to the confusion because some obtain only the  $\alpha$  (Examples 4 and 5) whereas others obtain the  $\alpha$  and  $\beta$  forms (Examples 2 and 3); this is further complicated by the fact that the protocols in the Examples follow the same steps." However, Applicants respectfully note that, while each of the examples employed a fermentation step (for the production of monomers), not all the examples employ the same extraction steps. Specifically, Examples 2, 4, and 5 employed fermentation, acidic/enzyme treatment, and precipitation while Example 3 employed only fermentation and acid/enzyme treatment without precipitation. In any event, each of the gel results show the production of mostly  $\alpha$  monomers in view of the darker staining of the smaller  $\alpha$ - form compared to the larger  $\beta$ - and/or  $\gamma$ - forms. Accordingly, and contrary to the assertion of the Office, the specification and examples demonstrate obtaining a collagen composition comprising mostly collagen monomers by following the claimed method involving fermentation, acid/enzyme treatment, and precipitation.

Moreover, it is well established that an inventor need not provide the explanation for how an invention actually works--the inventor must only describe and enable the invention. See, *Fromson v. Advance Offset Plate, Inc.* 720 F.2d 1565, 1570 (Fed. Cir. 1983) ("[I]t is axiomatic that an inventor need not comprehend the scientific principles on

which the practical effectiveness of his invention rests.") and *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989) ("[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works"). Accordingly, whether or not Applicants know precisely how fermentation ultimately produces the mostly collagen monomers is simply irrelevant, so long as Applicants have described and enabled the invention as claimed.

In view of the foregoing remarks, Applicants submit that the specification fully enables the claims. Withdrawal of the rejection of claims 54-76 is respectfully requested.

### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims. If the Office does not consider the application to be allowable, Applicants respectfully request that the Office contact their representative set up an interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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